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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY TICKET NO.	CONFIRMATION NO.
11/871,901	10/12/2007	Morteza Naghavi	662-0002USC	7773

29855 7590 06/23/2010  
WONG, CABELLO, LUTSCH, RUTHERFORD & BRUCCULERI,  
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HOUSTON, TX 77070

EXAMINER

TOWA, RENE T

ART UNIT	PAPER NUMBER
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3736

MAIL DATE	DELIVERY MODE
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06/23/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

RECEIVED  
WONG CABELLO

JUN 28 2010

**Office Action Summary**

Application No.

11/871,901

Applicant(s)

NAGHAVI ET AL.

Examiner

RENE TOWA

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 11/21/08.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. **Claims 1-3, 5-6, 9, 12-13, 16 & 19** are rejected under 35 U.S.C. 102(e) as being anticipated by Bowman et al. (US 2003/0191395).

In regards to **claim 1**, Bowman et al. disclose a method for assessing vascular function, comprising:

- a. providing a vasodilating stimulant to a patient to stimulate hemodynamic activity in a selected region of the patient's body;
  - b. monitoring a change in the hemodynamic parameter at the selected region;
- and
- c. assessing the patient's vascular function based upon the monitoring (see fig. 1; see par 0014-0016, 0038 & 0040).

In regards to **claim 2**, Bowman et al. disclose a method, wherein providing a vasodilating stimulant comprises:

- a. occluding blood flow to the selected region for a predetermined period of time;
- and

b. ceasing the occlusion after the predetermined period of time (see par 0015 & 0023).

In regards to **claim 3**, Bowman et al. disclose a method, wherein the hemodynamic parameter is temperature (see par 0040).

In regards to **claim 5**, Bowman et al. disclose a method, wherein providing a vasodilating stimulant comprises occluding blood flow to an arm (see par 0023, 0036 & 0043).

In regards to **claim 6**, Bowman et al. disclose a method, wherein said monitoring occurs from a time prior to the beginning of said compression until a time after the hemodynamic parameter has stabilized (see par 0037).

In regards to **claim 9**, Bowman et al. disclose a method for assessing vascular function in a patient, comprising:

a) measuring a stable baseline temperature at a selected region of the patient (see par 0038);

b) providing a vasostimulant to the patient (see par 0016 & 0046);

c) measuring a change in temperature at the selected region after provision of the vasostimulant (see par 0040);

d) assessing the patient's vascular function based upon the temperature change (see par 0040).

In regards to **claim 12**, Bowman et al. disclose a method, wherein providing a vasostimulant comprises occluding blood flow to the selected region for a predetermined period of time and ceasing compression after the predetermined period

of time, wherein the selected region comprises an arm (see par 0015, 0023, 0036 & 0043).

In regards to **claim 13**, Bowman et al. disclose a method, wherein the measuring is conducted from a time prior to the administration of the vasostimulant until a time after a stable temperature is reached after provision of the vasostimulant (see par 0038).

In regards to **claim 16**, Bowman et al. disclose a method for determining a vascular function status in a patient comprising:

- a) initiating monitoring of temperature at a selected region of the patient until a stable temperature is reached (see par 0036-0038);
- b) while continuing the monitoring, occluding blood flow to the selected region for a predetermined period of time to stimulate hemodynamic activity, and ceasing the occlusion after the predetermined period of time (see par 0015);
- c) continuing monitoring of the temperature until the temperature of the selected region has stabilized after ceasing the occlusion (see par 0037-0038); and
- d) assessing the patient's vascular function status based upon changes in the monitored temperature (see par 0038).

In regards to **claim 19**, Bowman et al. disclose a method wherein the blood flow is occluded at an arm (see par 0015, 0023, 0036 & 0043).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 4, 7, 10-11, 14 & 17-18** are rejected under 35 U.S.C. 103(a) as obvious over Bowman et al. (US 2003/0191395) in view of Barnea (US 6,117,075).

*Bowman et al. disclose a method, as described above, that fails to explicitly teach a plot of temperature versus time.*

However, Barnea teaches that it is known to provide a plot of temperature versus time (see fig. 2); wherein the selected region is a digit on a fingertip (see fig. 5).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the method of Bowman et al. with a plot of temperature versus time as taught by Barnea in order to facilitate comparison of the measured parameters.

5. **Claims 8, 15 & 20** are rejected under 35 U.S.C. 103(a) as obvious over Bowman et al. (US 2003/0191395) in view of Zheng et al. (US 6,447,460).

*Bowman et al. disclose a method, as described above, that fails to explicitly teach an ultrasound Doppler or a pulse wave velocity parameter.*

However, Zheng et al. disclose(s) a thermal energy measurement apparatus, wherein the device further comprises a unit for measuring a hemodynamic parameter such as blood flow velocity using ultrasound Doppler (see abstract; see figs. 2 & 5).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the method of Bowman et al. with an

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ultrasound Doppler as taught by Zheng et al. in order to screen for deep vein Thrombosis.

**Conclusion**

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENE TOWA whose telephone number is (571)272-8758. The examiner can normally be reached on Mon-Thurs, 8:00AM-6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rene Towa/  
Examiner, Art Unit 3736

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/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736